DEPARTMENT OF HEALTH & HUMAN SERVICES

RB 8/5/99 M2843N

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

August 5, 1999

WARNING LETTER

Ronald G. Thompson, President
Primus Sterilizer Co., Inc.
117 South 25th Street
Omaha, NE 68111

KAN #99-024

Dear Mr. Thompson:

We are writing to you because on March 23 through 31, 1999, a FDA Investigator from this office conducted an inspection of your facility located at 4256 Redman Avenue, Omaha, Nebraska, which revealed a serious regulatory problem involving your clinical steam sterilizers.

Under the Federal Food, Drug, and Cosmetic Act (Act), clinical steam sterilizers are considered to be medical devices. The law requires that manufacturers of medical devices adhere to the Quality System Regulations. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the applicable requirements of Section 520(f)(1)(A) and the Quality System Regulation, promulgated thereunder in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to have a management system in place which insures medical devices are manufactured in accordance with the QSR regulations. Examples include:

  - No written procedures for quality audits and none performed.
  - No written procedures for management review and none performed.
  - No written quality policy or quality plan.
  - No documentation of an appointed management representative.

- Failure to have a written procedure for document control, and current procedures have no document control

- Failure of the change control procedure entitled "Drawings and Specifications" to identify when to perform verification or validation on changes, nor the mechanism to do this.

- Failure of the procedure entitled "Final Inspection, Examination, and Testing" to described all final testing necessary to release a lot.

- Failure of the procedure entitled "Correction of Non-Conformities" to describe the evaluation, segregation, and the determination for the need to investigate the non-conformance.

- Failure to have device master records for the clinical sterilizers, which would include references to the locations of master record components.

- Failure to have complete and accurate device history records as evidenced by the following:

    - Device history records do not document who calibrates the sterilizer prior to testing.
    - Device history record for sterilizer with serial no. 15251 does not include the programmed cycle parameters or the test results.
    - Device history record for sterilizer with serial no. 15488 does not include a copy of the PSS500 controller QC checklist.

- Failure to have an adequate complaint handling system in that there is no evaluation to determine if an investigation is needed; insufficient information is obtained for evaluation; no written procedure for implementing corrective and preventative action; complaint data is not analyzed to identify potential problems.

- Failure of the procedure entitled "Complaint Handling Failure Investigation" to describe reporting requirements to FDA for MDR reportable complaints, and the timeframes for this reporting.

In addition, the Primus Steam Sterilizer Models 520VS-R-38 and 520VS-C-38, are adulterated under Section 501(f)(1)(B) of the Act because they are considered to be Class III devices under section 513(f), which are not exempt under 520(g), and are required to have in effect an approved application for premarket approval, and no such approval is in effect for them.

Furthermore, the Primus Steam Sterilizer Models 520VS-R-38 and 520VS-C-38, are misbranded within the meaning of Section 502(o) in that a notice or other information respecting the devices has not been provided to the FDA as required by 21 CFR 807.81(a)(3)(ii) for new intended uses, such as a flash cycle.

This letter is not intended to be an all-inclusive list of deficiencies at this facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the conclusion of the inspection Form FDA 483 was issued to, and discussed with you. This is a list of the QSR deviations made by the Investigator during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District